

## **REMARKS**

### **Amendments to the Specification**

The specification has been amended to correct obvious spelling errors at pages 15 and 28, and to correct the address of the American Type Culture Collection as required by the Examiner.

The specification has also been amended to include material that was originally incorporated by reference. Specifically, the specification has been amended to include Examples 5 and 6 from the priority document, U.S. Application Serial No. 10/276,358, which was incorporated by reference in its entirety on page 1, lines 35-36 of this application. The requisite declaration executed by the below-named agent is also enclosed herewith, which states that the amendatory material consists of the same material incorporated by reference into the specification. The Examples have been renumbered as Examples 35 and 36, to track the numbering of Examples in the present application. The Tables within these Examples have similarly been renumbered as Tables 17 and 18, again to track the numbering of Tables in the present application.

### **Amendments to the Claims**

Claims 44, 46, 49, 66, 69 and 70 have been cancelled, without prejudice to or disclaimer of the subject matter therein.

Claim 45 has been amended to remove certain variants in an effort to expedite prosecution, and to add particular variants that are described in the new Examples 35 and 36 discussed above.

Claim 71 has been added to add a particular variant that is described in Examples 35 and 36 as discussed above.

All remaining amendments are clerical in nature, and mainly intended to change claim dependencies.

### **Objections to the Specification**

The Examiner has objected to the specification for spelling errors on page 15 and 28 and for an incorrect address on page 57. The specification has been amended to address these objections.

Objection to the Specification and Rejection of Claims 44-70 Under 35 U.S.C. § 112, First Paragraph:

The Examiner has objected to the specification and rejected Claims 44 and 45, as well as 46-70 (as dependent claims) under 35 U.S.C. § 112, first paragraph, on the basis of enablement. The Examiner states that the specification is enabling for those IFN- $\alpha$ 2 cysteine variants disclosed in WO 01/87925, but contends that the specification does not provide enablement for the other cysteine variants that are not part of that recitation and accordingly, located in the regions of IFN- $\alpha$ 2 that contain such alleged non-enabled constructs. The Examiner lists specific positions and regions of IFN- $\alpha$ 2 that are not deemed to be enabled on page 4 of the specification. The Examiner additionally contends that the specification does not enable prophylactic protection from a disease and indicates that Claim 44 should be limited to the definition presented on page 23, lines 25-27 of the specification.

Initially, it is noted that Claims 44, 46, 49, and 66 have been cancelled, without prejudice to or disclaimer of the subject matter therein. Therefore, claims directed to the regions of IFN- $\alpha$ 2 are no longer present in the instant claims. Claim 45 and dependent claims therefrom, have been amended to recite only those cysteine variants of IFN- $\alpha$ 2 that have been produced and for which biological activity has been demonstrated, as illustrated by experiments provided in the present application and the priority documents. Applicants note, however, that certain of the variants listed in the Examiner's group of those variants as not being enabled, namely, R162, S163, K164 and E165, are in fact demonstrated in WO 01/87925 in Example 5 and Example 6, Tables 4 and 5 (and therefore in the national stage filing of that application, U.S. Application Serial No. 10/276,358, which is a priority document for the present application, and which was incorporated by reference in its entirety on page 1, lines 35-36 of this application). These Examples have now been added to the present specification as discussed above, and accordingly it is believed that recitation of these variants meets the requirements of written description and enablement. Moreover, since the new Examples also list additional active cysteine variants of IFN- $\alpha$ 2 that were produced, these have been added to Claim 45, since the specification now literally supports the addition of these variants.

With regard to the language "protect" in Claim 44, Applicants note that Claim 45, in being amended as the independent claim, now recites the language suggested by the Examiner, as supported by the specification on page 23, lines 25-27. Therefore, this portion of the rejection

is believed to be moot.

In view of the foregoing remarks, the Examiner is respectfully requested to withdraw the rejection of Claims 44-70 under 35 U.S.C. § 112, first paragraph.

Objection to the Specification and Rejection of Claim 68 Under 35 U.S.C. § 112, First Paragraph:

The Examiner has objected to the specification and rejected Claim 68, on the basis of written description. The Examiner asserts that the mutant R23K has not been described at all in the specification and was added in the Applicants' response after restriction.

Applicants traverse the rejection of Claim 68 under 35 U.S.C. § 112, first paragraph. Referring to page 56, lines 6-7, the specification teaches:

"There are two subtypes of the alpha-2 interferon protein; one subtype has arginine at position 23 whereas the other subtype has lysine at position 23."

The sequence represented in the specification as SEQ ID NO:3 contains the arginine at position 23. Accordingly, Claim 68 was intended to convey the presence of the lysine at position 23, which is taught by the specification to be a "natural" substitution at this position. Therefore, Applicants believe that this claim is fully supported by the specification.

In view of the foregoing remarks, the Examiner is respectfully requested to withdraw the rejection of Claim 68 under 35 U.S.C. § 112, first paragraph.

Rejection of Claims 44, 52-62 and 70 Under 35 U.S.C. §103(a):

The Examiner has rejected Claims 44, 52-62 and 70 under 35 U.S.C. § 103(a), contending that these claims are unpatentable over Glue et al. in view of Katre et al.

Applicants note that Claims 44 and 70 have been cancelled without prejudice to or disclaimer of the subject matter therein, and that Claims 52-62 have been amended to depend from Claim 45. Therefore the rejection is believed to be moot and its withdrawal is respectfully requested.

Applicants have attempted to respond to all of the Examiner's rejections and submit that the claims are in a condition for allowance. Any further questions or concerns regarding Applicants' position should be directed to the below-named agent at (303) 863-9700 in the

interest of expediting prosecution.

Respectfully submitted,

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